Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative study of the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Protocol summary

Study aim
Comparative study of the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Design
This is single blind clinical trial.The study population included all patients referring to Imam Reza hospital in Kermanshah city. A total of 148 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct
This study, which will be conducted at Imam Reza Hospital in Kermanshah city. The participants do not know what medicine they will receive, and at the beginning of the study, the vital signs of the participants in both groups are recorded in a checklist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: no history of previous cesarean section or any uterine scar; single pregnancy. Exclusion criteria: estimate fetal weight more than 4 kg; labor pain.

Intervention groups
The first intervention group will receive 40 mg of vaginal isosorbide dinitrate within 24 hours.The second intervention group will receive 20 mg of vaginal isosorbide dinitrate within 24 hours.The third intervention group will receive 10 mg of vaginal isosorbide dinitrate within 24 hours.The control group will not receive any intervention.

Main outcome variables
Headache, nausea, blood pressure drop

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N90**
Registration date: **2018-05-02, 1397/02/12**
Registration timing: **registered_while_recruiting**
Last update: **2018-05-02, 1397/02/12**
Update count: **0**

Registration date
2018-05-02, 1397/02/12

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-28, 1397/02/08

Expected recruitment end date
2018-10-30, 1397/08/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Public title
Comparison the effect of vaginal isosorbide dinitrate in pre-induction cervical ripening in term pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 37 weeks up to the end of the week Cephalic presentation No contraindications for isosorbide dinitrate Normal body volume index (BMI = 19.8-26), No history of previous cesarean section or any uterine scar

Exclusion criteria:

The presence of systemic diseases Estimate fetal weight more than 4 kg Vaginal bleeding Intolerance to ISDN, labor pain and oligohydramnios

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients will be blinded to the study groups, dosage of the drug and the manufacturer of the drug

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-01-31, 1396/11/11

Ethics committee reference number

IR.KUMS.REC.1396.594

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

Z34

ICD-10 code description

Normal pregnancy

Primary outcomes

1

Description

Headache

Timepoint

At the beginning of the study, every 15 minutes to 1 hour, then every 30 minutes to 2 hours, and every 1 hour until delivery

Method of measurement

Ask the patient

2

Description

Nausea

Timepoint

At the beginning of the study, every 15 minutes to 1 hour, then every 30 minutes to 2 hours, and every 1 hour until delivery

Method of measurement

Ask the patient

3

Description

Blood pressure drop

Timepoint

At the beginning of the study, every 15 minutes to 1 hour, then every 30 minutes to 2 hours, and every 1 hour until delivery

Method of measurement

Sphygmomanometer.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 40 mg of vaginal isosorbide dinitrate within 24 hours

Category

Treatment - Drugs

2

Description
The second intervention group will receive 20 mg of vaginal isosorbide dinitrate within 24 hours
Category
Treatment - Drugs

3

Description
The third intervention group will receive 10 mg of vaginal isosorbide dinitrate within 24 hours
Category
Treatment - Drugs

4

Description
The control group will not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Fatemeh Poyan
Street address
Emam Reza Hospital, Parastar Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
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+98 83 3836 0014
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fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
fatemeh poyan
Position
Resident of Obstetrics and Gynecology
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
6 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
To receive the documentation, email send for update manager
What processes are involved for a request to access data/document
In a 15-day period, the documents will be sent e-mail
Comments